

Draft 1-Materials Committee
Recommendation to add Board Policy Manual to Update the Materials Review
Process
Last version 2/7/2005

Evaluation Procedures for Substances Petitioned for Addition or Removal from
the National List

Phase 1: Receipt of Petition

During this phase the National Organic Program (NOP) will:

- Notify the petitioner via letter and/or electronic mail of receipt of the petition.

Phase 2: Examination of Petition for Completeness and Eligibility

During this phase the NOP will:

- Determine whether the petition is complete
- Determine if the petitioned substance is eligible for petition under the Organic Foods Production Act and its implementing regulations; document this review using the NOP-OFPA checklist.
- Determine whether the petitioned use is approved under the statutory and regulatory authority of the Environmental Protection Agency (EPA) or the Food and Drug Administration (FDA) if applicable;
- Identify and secure any confidential business information (CBI) designated by the petitioner;
- Notify, as applicable, the petitioner via letter and/or electronic mail of determination of completeness and eligibility, and acknowledging the designation of certain information as CBI.
- Upon determination of completeness and eligibility, the following actions will be taken:
 - Publish the petition on NOP website; and
 - Notify the National Organic Standards Board (NOSB) materials committee chairperson and the chairperson of the committee that the substance is being petitioned for addition or prohibition from the National list (Crops, Livestock or Handling). This notification will sent via letter and/or electronic mail and inform the chairs that the petition is complete, provide OFPA review and EPA/FDA determination checklist, and request identification of any questions the appropriate committee wishes to be specifically addressed in the contractor's report. The NOSB materials committee, working with other applicable NOSB committees, has 21 working days to submit any questions to the NOP. The questions requested by the committee

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- should include items that need specific background information provided and be based on the OFPS criteria.
 - Notify the contractor of the determination of completeness and eligibility via letter and/or electronic mail. This letter will constitute official notice to the contractor to perform an evaluation of the petitioned substance.
- Notify, as applicable, the petitioner via letter and/or electronic mail of determining the petition to be incomplete or ineligible.

Phase 3: Evaluation by Contractor

During this phase, the contractor will:

- Conduct activities necessary to provide responses to evaluation questions contained in the Statement of Work and any additional questions identified by the NOSB as described above;
- Using the evaluation report template, prepare and distribute to the NOP a draft evaluation report in electronic format.

Phase 4: Sufficiency Determination

During this phase, the NOP will:

- Submit a copy of the draft evaluation report to the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National list (Crops, Livestock or Handling) for its review;
- Review the draft evaluation report against the following performance criteria. The report will be acceptable when it:
 - Is consistent in format, level of detail and tone;
 - Is technically objective and free from opinions or conjecture;
 - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
 - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
 - Is based on the best available information that can be obtained within the designated time frame;
 - Is thoroughly supported using literature citations; and,
 - Addresses all evaluation questions as set out in the SOW.

During this phase, the NOSB materials committee and the committee that the substance is being petitioned for addition or prohibition from the National list (Crops, Livestock or Handling) will:

- Review the draft evaluation report against the following performance criteria. The report will be acceptable when it:
 - Is consistent in format, level of detail and tone;

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- Is technically objective and free from opinions or conjecture;
 - Is written in a style appropriate for non-technical readers (e.g. free of technical jargon);
 - Is prepared using a well-defined and consistent procedure consisting of information gathering, information synthesis and document preparation, and quality assurance;
 - Is based on the best available information that can be obtained within the designated time frame;
 - Is thoroughly supported using literature citations; and,
 - Addresses all evaluation questions as set out in the SOW.
- Notify the NOP in letter and/or electronic mail the acceptance of the report within 21 days of receiving the draft report. If the report is not accepted by the NOSB materials and the committee that the substance is being petitioned for addition or prohibition from the National list (Crops, Livestock or Handling), the committees must provide to the NOP in letter and/or electronic mail the specific areas of the report that were concluded to be insufficient, the rationale for drawing such a conclusion and the improvements to be made so that the document can be determined sufficient.
 - Upon concurrence by the NOP that the report is insufficient, the NOP will notify the contractor by letter and/or electronic mail of the areas of the report that are insufficient, the rationale for drawing such a conclusion and the improvements to be made so that the document can be determined sufficient. The time frame required for the completion of the changes will be determined through mutual agreement between the contractor and the NOP.

Phase 5: Action by NOSB Materials Chairperson and the committee that the substance is being petitioned for addition or prohibition from the National list (Crops, Livestock or Handling

During this phase the NOSB materials chairperson and the committee that the substance is being petitioned for addition or prohibition from the National list (Crops, Livestock or Handling will:

- Convene at a mutually convenient time to review, discuss and recommend an action on the petitioned substance. The committee may convene a Technical Advisory Panel by electronic mail or conference call to provide scientific evaluation of the petitioned substance, as provided by OFPA 6518(k)(3). The NOSB materials committee or delegated committee must convene and recommend an action on the petitioned substance no later than 30 days before a scheduled meeting of the full NOSB.

During this phase the NOP will:

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Publish the recommendation of the NOSB materials committee the committee that the substance is being petitioned for addition or prohibition from the National list (Crops, Livestock or Handling

- on the NOP website and request public comment on the recommendation.

Phase 6: Action by full NOSB

During this phase the NOP will:

- Set as an agenda item for the next meeting of the NOSB time sufficient to discuss and make a recommendation by the full NOSB on the petitioned substance.

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